

Batch Recalls in Switzerland 2009

Recalls from January 1, 2009 until December 31, 2009. All recalls are published in the Swissmedic Journal and on the Swissmedic website.
Classification of recalls according to the PIC/S standard operating procedure " Procedure for handling rapid alerts and recalls arising from quality defects".

Date of Recall Initiated	No of Product Licence	Brand Name	Dosage Form	Strength	Active Substance	Lot No	Marketing Authorization Holder	Class of Recall	Details of Defect
03. Dez. 2009	57'656	Amlodipin Spirig	Tablet	10mg	Amlodipinum	GATL08017	Spirig Pharma AG	I	Mix-up in containers (Amlodipine 5 mg)
26. Nov. 2009	54'839	Implanon	Implant		Etonogestrelum	448907/558771; /507352	Essex Chemie AG	II	difficult expulsion of implant from the applicator
10. Nov. 2009	54'842	CoAprovel/ Aprovel	Coated tablets	150mg + 12,5mg/150 mg	irbesartanum, hydrochlorothiazidum	8V018 / 9V017	Sanofi/Bristol-Myers Squibb SA, Meyrin	II	Mix-up of Aprovel in a container of Coaprovel
15. Okt. 2009	29'349	Prednison Streuli	Tablet	5mg	Prednisonum	0900081	Streuli Pharma AG	I	Mix-up or products in containers (blisters with Caniphedrin 20 mg ad us. vet.)
04. Sep. 2009	53'588	Thymoglobuline	Solution for infusion	25mg	immunoglobulinum antithymocyticum cuniculi	TH194-H01	Genzyme GmbH	III	potentially opalescent appearance of solution
26. Aug. 2009	37'404	Floxapen	Parenteral preparation	1g	Flucloxacillinum	80741	Actavis Switzerland AG	II	white powder inside the package on the outside of the vials
18. Aug. 2009	53'674	Lacrycon, Augen-Gel	Eye gel	0.14mg/ml	Acidum Hyaluronicum Acidum hyalutonicum, Natrii hyaluronicum	T229	Théa Pharma SA	II	Mix-up or products in containers (rogues)
20. Jul. 2009	57'521	Clavubactin ad us. vet.	Tablet	50/12,5mg	clavulanic acid, amoxicillin	080723	Dr. E. Gräub AG	II	Subpotency

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10. Jul. 2009	56'169	Rhinathiol Sirup ohne Zucker Kinder	Syrup	100mg/ 5 ml	Carbocisteinum	43	Sanofi-Aventis (Suisse) SA	II	Contamination, microbial of non-sterile product
09. Jul. 2009	56'414	Conoxia	Gas	3.5 l and 2.0 l	oxygenum medicinalis	see detailed publication	PanGas	III	Container valve defect
09. Jul. 2009	56'417	Distickstoffoxid medizinial	Gas	3.l and 4 l	dinitrogen oxyde	see detailed publication	PanGas	III	Container valve defect
09. Jul. 2009	56'418	Kohlendioxid medizinial	Gas	3.0 l	carbon dioxyde	see detailed publication	PanGas	III	Container valve defect
12. Jun. 2009	58'378	Cefepime OrPha	Powder for infusion	2 g	Cefepimum	OPMIF8003	Orpha Swiss GmbH	II	Contamination, physical
07. Mai. 2009	31'665	Becotal	Solution for injection	2 ml	B-Vitamine- Complex	all batches	Streuli Pharma AG	III	Turbidity / precipitate during storage
17. Apr. 2009	52'267	Lorasifar	Coated tablets	2.5mg	Lorazepamum	6984	Siphar SA, Lugano	II	Specifications not met
06. Apr. 2009	54'975	Seretide Diskus 250	Powder for inhalation	50 mcg / 250 mcg	Salmeterolum, Fluticasone -17 propionas	R356548	GlaxoSmithKline AG	II	complaint of with a torn foil strip, no further doses were discharged
04. Apr. 2009	52'780	Glycophos	Concentrate for solution for infusion	2.16 g/ 10 ml	Natrii glycerophosphas	12BIL03	Fresenius Kabi AG	II	Suspected container defect, white criystals (active substance) on the outer surface of single ampoules

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01. Apr. 2009	57'753	Nogynex (Co- marketing preparation of Benzaltex tampons 44'590)	Medicated vaginal tampon	12mg/g	Benzalconii chloridum	all batches	Interlabo Switzerland Sàrl, 1205 Genève	II	Non-compliance with specification (fill/weight). Stability data failing to support expiration date. Significant loss of humidity and dehydration of tampons
12. Mrz. 2009	56'813	Nebido	Solution for injection	1 g/4 ml	Testosteroni undecanoas	82008E	Bayer (Schweiz) AG	III	Container defect, breakage of ampoules during opening
03. Mrz. 2009	99'999	Weleda, various preparations	Solution for injection	various	Helleborus praep./Capsella busa-pastoris/Levisticum eth. Decoct/Cichorumplumbo cult./Nasturtium mercurio cult./	all batches	Weleda AG	II	Non-compliance with GMP
20. Feb. 2009	57'226	Hämopressin	Powder and solvent for solution for infusion	1 mg	Terlipressin	all batches	Proreo Pharma AG	II	Deviation from GMP
11. Feb. 2009	56'775	Gynazole-1	Vaginal cream	20mg	Butoconazoli nitras	80462	OM Pharma	III	Non-compliance with GMP (active substance)
07. Feb. 2009	52'041	NaCl 0.9% Bioren	Solution for infusion	9mg/ml	Natrii chloridum	08112272, 08112278	Sintetica-Bioren SA, Couvet	II	Contamination, chemical
06. Feb. 2009	23'527	Prazine	Coated tablets	25mg / 50mg	Promazini hydrochloridum	8087	Tentan AG	II	Labeling mix-ups
27. Jan. 2009	15'160	Protamin Valeant	Solution for injection	1000 I.E./ml, 5000 I.E./ml	Protamini hydrochloridum	705210, 702304, 702406, 802507,	Valeant Pharmaceuticals Switzerland GmbH	III	Non-compliance with specification (assay)